

Attorney Docket No.: DEX-0289
Inventors: Macina et al.
Serial No.: 09/989,919
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REMARKS

Claims 1-17 are pending in the instant application. Claims 10-13, 16 and 17 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this amendment. Claims 1-9, 14 and 15 have been rejected. Claims 1, 6, 14 and 15 have been amended. Support for these amendments is provided in the specification at page 14, line 23, through page 17, line 4, and page 32, lines 25 through 29. Thus, no new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed May 2, 2003. Thus, in an earnest effort to facilitate the prosecution, Applicants have canceled non-elected claims 10-13, 16 and 17, without prejudice. In light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Objection to Disclosure

The Examiner has objected to the disclosure for containing embedded hyperlinks and/or other forms of browser-executable

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code. It is respectfully pointed out, however, that Applicants have no intention of having these hyperlinks be active links. Instead, these hyperlinks and/or other forms of browser-executable codes describe enabling methodologies for use with the claimed invention and therefore have been included in the patent application in order to comply with the requirements of 35 U.S.C. § 112, first paragraph. Thus, in accordance with MPEP § 608.01(p), Applicants should not be required to remove these citations from the specification.

Withdrawal of this objection is therefore respectfully requested.

III. Rejection of Claims 1-9, 14 and 15 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph

Claims 1-9, 14 and 15 have been rejected under 35 U.S.C. § 101 as the Examiner suggests that the claimed invention lacks patentable utility. Specifically, the Examiner suggests that the application does not disclose a connection between the presence or expression of SEQ ID NO:15 and colon cancer. Claims 1-9, 14 and 15 have also been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner suggests that the claims contain subject matter which was not described in the specification in such a way as to

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enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants respectfully traverse this rejection.

As taught in Example 1 beginning at page 116 of the instant application, the colon specific genes of the present invention including SEQ ID NO:15 which are useful as diagnostic markers for colon cancer (see specification beginning at page 95) were identified by mRNA subtraction analysis using standard methods. It was well known in the art at the time of filing that PCR based subtractive hybridization methods are designed to selectively enrich for cDNAs corresponding to mRNAs differentially expressed between two mRNA populations (Diatchenko et al. Proc. Natl Acad. Sci. USA 1996 93:6025-6030). Furthermore, it was well known in the art that mRNA populations can be isolated from cancer tissue and normal tissue or normal adjacent tissue to selectively enrich for cDNAs corresponding to mRNAs which are over-expressed in cancer tissue. Thus, contrary to the Examiner's suggestion, the subtraction analysis data of Example 1 provides a connection between the presence or expression of SEQ ID NO:15 and colon cancer and establishes a utility for SEQ ID NO:15 which meets the requirements of 35 U.S.C. § 101 and § 112, first paragraph.

Withdrawal of these rejections under 35 U.S.C. § 101 and §

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112, first paragraph, is therefore respectfully requested.

IV. Rejection of Claims 1-9, 14 and 15 under 35 U.S.C. § 112,
second paragraph

Claims 1-9, 14 and 15 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner suggests that claims 1, 14 and 15 are vague and indefinite because they claim more than was elected.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended these claims to be drawn only to the elected subject matter.

The Examiner also suggests that the recitation of "selectively hybridizes" in claim 1 and 6 is vague, indefinite, and incomplete because the term is a relative one and no frame of reference is given.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have replaced the term "selectively hybridizes" with "stringent hybridization". The conditions for stringent hybridization are outlined in detail in the specification at page 14, line 23, through page 17, line 4.

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Accordingly, what is meant by this phrase is clear when read in light of the specification and meets the requirements of 35 U.S.C. § 112, second paragraph as set forth in MPEP § 2173.02.

The Examiner also suggests that recitation of colon specific nucleic acid in claim 6 is vague and indefinite because the term is not clearly defined. Applicants respectfully traverse this rejection.

The phrase "colon specific nucleic acid" is specifically defined at page 6 as well as page 31 of the instant specification. Thus, what is meant by this phrase is clear when read in light of the specification as required by MPEP § 2173.02 and meets the requirements of 35 U.S.C. § 112, second paragraph.

The Examiner also suggests that the recitation of the colon specific marker in claim 14 is incomplete because the term lacks antecedent basis. Accordingly, Applicants have replaced this term with the phrase "nucleic acid molecule" for which there is clear antecedent basis.

Finally the Examiner suggests that recitation in claim 15 of "means for determining the presence of the nucleic acid molecule of claim 1" is vague and indefinite because such means are not clearly defined. Applicants respectfully disagree as means for determining the presence of nucleic acid sequences are set forth

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in detail at pages 95 through 99 of the instant specification. Thus, the claims, when read in light of the teachings in the specification as required by MPEP §2173.02 are clear with respect to what is meant by the recitation of "means for determining the presence of the nucleic acid molecule of claim 1" and therefore meet the requirements of 35 U.S.C. § 112, second paragraph.

Withdrawal of these rejections under 35 U.S.C. § 112, second paragraph, is respectfully requested in light of these arguments and the amendments to the claims.

V. Rejection of Claims 6, 14 and 15 under 35 U.S.C. § 112, first paragraph

Claim 6, 14 and 15 have been rejected under 35 U.S.C. § 112, first paragraph, as the Examiner suggests that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The Examiner has acknowledged the specification to be enabling for specific hybridization using probes that have 100% sequence identity to SEQ ID NO:15. However, the Examiner suggests that the specification does not reasonably provide enablement for specific hybridization using probes less than 100% identical to SEQ ID NO:15.

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Applicants respectfully traverse this rejection.

Probes and primers for use in the present invention are described in detail at pages 41-44 of the instant application. As discussed therein, methods for use of such probes and primers are well known and 100% sequence identity to the target is not required for their use as claimed.

It is therefore respectfully requested that this rejection under 35 U.S.C. § 112, first paragraph be withdrawn.

VI. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. § 102(a)

Claims 1-5, 7-9 and 15 have been rejected under 35 U.S.C. § 102(a) as being anticipated by one of Rosen et al. (WO 01/55323) or Plowman (WO 00/73469). The Examiner suggests that Rosen et al. discloses a DNA with 92% sequence similarity to SEQ ID NO:15 while Plowman discloses a DNA with 67.3% sequence similarity to SEQ ID NO:15.

Claims 1-5, 7 and 8 have also been rejected under 35 U.S.C. § 102(a) as being anticipated by Waterston et al. (GenBank Accession No. AC013480). The Examiner suggests that Waterston et al. discloses a DNA with 93.7% sequence similarity to SEQ ID NO:15.

Thus, in an earnest effort to advance the prosecution of this case and to clearly distinguish the present invention from

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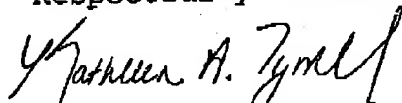
teachings of Rosen, Plowman or Waterston et al., Applicants have amended the claims in accordance with teachings at page 32, line 25-29 to state that the nucleic acid molecule has at least 95% sequence identity to the nucleic acid molecule of SEQ ID NO:15. Accordingly, these reference do not teach all the elements of the claimed invention and cannot anticipate the claimed invention.

Withdrawal of these rejections under 35 U.S.C. § 102 is therefore respectfully requested.

VII. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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